CLAIMS

What we claim is:

1. A method for treating a respiratory ailment comprising the step of:

administering a therapeutically effective amount of a respiratory drug condensation aerosol to a person with the respiratory ailment, wherein the step of administering comprises the step of administering an orally inhalable respiratory drug condensation aerosol to the person with the respiratory ailment, and wherein the aerosol comprises at least 50% by weight of a respiratory drug.

2. The method of claim 1 wherein the respiratory drug is selected from the group consisting of β-adrenergics, methylxanthines, anticholinergics, corticosteroids, mediator-release inhibitors, anti-leukotriene drugs, asthma inhibitors, asthma antagonists, anti-endothelin drugs, prostacyclin drugs, ion channel or pump inhibitors, enhancers, or modulators and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

3. The method of claim 2 wherein the respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan,

sitaxsentan, tezosentan, iloprost, treprostinil, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

4. The method of claim 1 wherein the respiratory drug condensation aerosol has a MMAD in the range of about 1.5-4 μm.

5. The method of claim 1 wherein the respiratory drug condensation aerosol has a MMAD in the range of about 10-100 nm.

6. The method of claim 1 wherein the step of administering the respiratory drug condensation aerosol comprises the step of administering the respiratory drug condensation aerosol in a single inhalation.

7. The method of claim 1 wherein the step of administering the respiratory drug condensation aerosol comprises the step of administering the respiratory drug condensation aerosol in more than one inhalation.

8. A method for forming a respiratory drug condensation aerosol comprising the steps of:

providing a respiratory drug composition in a unit dose form; and

vaporizing the respiratory drug composition, wherein the step of vaporizing the respiratory drug composition comprises the step of heating the composition to form a vapor.

9. The method of claim 8 wherein the respiratory drug composition comprises a respiratory drug selected from the group consisting of β-adrenergics, methylxanthines, anticholinergics, corticosteroids, mediator-release inhibitors, anti-leukotriene drugs, asthma inhibitors, asthma antagonists, anti-endothelin drugs, prostacyclin drugs, ion channel or pump inhibitors, enhancers, or modulators, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

10. The respiratory drug condensation aerosol of claim 9 wherein the respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline,

pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

11. The method of claim 8 wherein the respiratory drug composition further comprises a pharmaceutically acceptable excipient.

12. The method of claim 8 wherein the respiratory drug condensation aerosol comprises at least 50% by weight of a respiratory drug.

13. A respiratory drug condensation aerosol comprising:

respiratory drug condensation aerosol particles, wherein the respiratory drug aerosol particles comprise a respiratory drug selected from the group consisting of β-adrenergics, methylxanthines, anticholinergics, corticosteroids, mediator-release inhibitors, anti-leukotriene drugs, asthma inhibitors, asthma antagonists, anti-endothelin drugs, prostacyclin drugs, ion channel or pump inhibitors, enhancers, or modulators, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof, and wherein the respiratory drug condensation aerosol has a MMAD in the range of about 2-4 μm.

14. The respiratory drug condensation aerosol of claim 13 wherein the respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline,

pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

15. The respiratory drug condensation aerosol of claim 13 wherein the aerosol comprises at least 50% by weight of a respiratory drug.

16. The respiratory drug condensation aerosol of claim 13 wherein the aerosol is substantially free of thermal degradation products.

17. A kit for delivering a respiratory drug condensation aerosol comprising:

a composition comprising a respiratory drug in a unit dose form; and

a device for forming a respiratory drug aerosol, wherein the device for forming the respiratory drug aerosol comprises an element configured to heat the composition to form a vapor, an element allowing the vapor to condense to form a condensation aerosol, and an element permitting a user to inhale the condensation aerosol.

18. The kit of claim 17 wherein the composition further comprises a pharmaceutically acceptable excipient.

19. The kit of claim 17 wherein the respiratory drug condensation aerosol comprises at least 50% by weight of a respiratory drug.

20. The kit of claim 17 wherein the respiratory drug is selected from the group consisting of β-adrenergics, methylxanthines, anticholinergics, corticosteroids, mediator-release inhibitors, anti-leukotriene drugs, asthma inhibitors, asthma antagonists, anti-endothelin drugs, prostacyclin drugs, ion channel or pump inhibitors, enhancers, or modulators, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

21. The kit of claim 20 wherein the respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

22. A method for treating a respiratory ailment comprising the step of:

administering a therapeutically effective amount of a respiratory drug condensation aerosol to a person with the respiratory ailment, wherein the respiratory drug aerosol comprises a respiratory drug and has a MMAD in the range of about 1.5-4 μm and a purity of at least 90%, and

wherein the step of administering comprises the step of administering an orally inhalable respiratory drug aerosol to the person with the respiratory ailment.

23. The method of claim 22 wherein the respiratory drug is selected from the group consisting of β-adrenergics, methylxanthines, anticholinergics, corticosteroids, mediator-release inhibitors, anti-leukotriene drugs, asthma inhibitors, asthma antagonists, endothelin antagonists, prostacylins, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

24. The method of claim 23 wherein the respiratory drug is selected from the group consisting of albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

25. A composition for delivery of a drug comprising a respiratory drug condensation aerosol

a) formed by volatilizing a heat stable drug composition comprising a respiratory drug selected from the group consisting of β-adrenergics, methylxanthines, anticholinergics, corticosteroids, mediator-release inhibitors, anti-leukotriene drugs, asthma inhibitors, asthma antagonists, anti-endothelin drugs, prostacyclin drugs, ion channel or pump

inhibitors, enhancers, or modulators under conditions effective to produce a heated vapor of said drug composition and condensing the heated vapor of the drug composition to form condensation aerosol particles and wherein the respiratory drug condensation aerosol has a MMAD in the range of about 2-4 μm.

26. The composition of claim 25, wherein the heat stable drug is selected from the group consisting albuterol, epinephrine, metaproterenol, terbutaline, pseudoephedrine hydrochloride, bambuterol, bitolterol, carbuterol, clenbuterol, clorprenalin, dioxethedrine, eprozinol, etefedrine, ethylnorepinephrine, fenoterol, fenspiride, hexoprenaline, isoetharine, isoproterenol, mabuterol, methoxyphenamine, pirbuterol, procaterol, protokylol, rimiterol, salmeterol, soterenol, tretoquinol, tulobuterol, caffeine, theophylline, aminophylline, acefylline, bamifylline, doxofylline, dyphylline, etamiphyllin, etofylline, proxyphylline, reproterol, theobromine-1-acetic acid, atropine, ipratropium bromide, flutropium bromide, oxitropium bromide, tiotropium bromide, budesonide, beclomethasone, ciclesonide, dexamethasone, flunisolide, fluticasone propionate, triamcinolone acetonide, prednisolone, methylprednisolone, hydrocortisone, cromolyn sodium, nedocromil sodium, montelukast, zafirlukast, pirfenidone, CPX, IBMX, cilomilast, roflumilast, pumafentrine, domitroban, israpafant, ramatroban, seratrodast, tiaramide, zileuton, ambrisentan, bosentan, enrasentan, sitaxsentan, tezosentan, iloprost, treprostinil, and pharmaceutically acceptable analogs, derivatives, and mixtures thereof.

27. The composition of claim 25, wherein the condensation aerosol particles are characterized by less than 5% drug degradation products

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28. The composition of claim 25, wherein said drug composition comprises at least two drugs.

29. The composition of claim 28, wherein at least one drug of the drug composition is a reliever and another drug of the drug composition is a controller.

30. The composition of claim 29, wherein the reliever is a β-adrenergic.

31. The composition of claim 30, wherein the controller is a corticosteriod.

32. The composition of claim 29, wherein the controller is a corticosteriod.

33. A method for treating a respiratory ailment comprising the step of: administering a therapeutically effective amount of a respiratory drug condensation aerosol comprising a heat stable respiratory drug to a person with the respiratory ailment, wherein the step of administering comprises administering an orally inhalable respiratory drug condensation aerosol to the person with the respiratory ailment, and wherein the aerosol comprises at least 50% by weight of a respiratory drug.

34. A method of producing a heat stable respiratory drug in an aerosol form comprising:

a) volatilizing a heat stable respiratory drug under conditions effective to produce a heated vapor of the drug and

b) during said volatilizing, passing through the heated vapor to produce aerosol particles of the drug and an aerosol having an MMAD in the range of 1.5 – 4.

35. The method of claim 34, wherein the aerosol particles comprise less than 5% compound degradation products.

36. The method of claim 34, wherein said volatilizing includes heating a coating of the respiratory drug, which is formed on a solid support having the surface texture of a metal foil, to a temperature sufficient to volatized the compound from the coating.

37. The method of claim 36, wherein said coating comprises at least two respiratory drugs.

38. The method of claim 37, wherein at least one drug is a reliever and another drug is a controller.